IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AETHER THERAPEUTICS, INC., Plaintiff, v. ASTRAZENECA AB, ASTRAZENECA PHARMACEUTICALS LP, NEKTAR THERAPEUTICS and DAIICHI SANKYO, INC., Defendants.	)	C.A. No. 20-381 (MN)
AETHER THERAPEUTICS, INC., Plaintiff, v. REDHILL BIOPHARMA, INC., Defendant.	)	C.A. No. 21-248 (MN)

MEMORANDUM ORDER

At Wilmington this 17th day of September 2021:

As announced at the hearing on August 30, 2021 IT IS HEREBY ORDERED that the disputed claim terms of U.S. Patent Nos. 6,713,488 ("the '488 Patent"), 8,748,448 ("the '448 Patent"), 8,883,817 ("the '817 Patent") and 9,061,024 ("the '024 Patent") are construed as follows:

1. "unit dosage" means the opioid agonist and neutral opioid antagonist (and pharmaceutically acceptable carrier, where appropriate) are co-formulated in a single dosage form, *i.e.*, in one unit ('817 Patent, claims 1-17, 11, 15-17, 19-22 & 25; '024 Patent, claim 1; '448 Patent, claims 1, 2, 4, 5, 9 & 11)

2. "[naloxone / naltrexone] analog" will not be construed at this time ('488 Patent, claims 25-29)[1]

[1] The dispute over the meaning of the "analog" terms was whether the terms were indefinite. The Court found that indefiniteness had not been proven at this stage but left open the possibility that a separate indefiniteness hearing may be held (at the Court's discretion). If

The parties briefed the issues (*see* D.I. 88)[2] and submitted an appendix containing intrinsic and extrinsic evidence, including expert declarations (*see* D.I. 89), and Plaintiff Aether Therapeutics, Inc. provided a tutorial describing the relevant technology (D.I. 92).[3] Defendants also submitted transcripts of the expert depositions taken in connection with claim construction. (*See* D.I. 95; *see also* D.I. 96). The Court carefully reviewed all submissions in connection with the parties' contentions regarding the disputed claim terms, heard oral argument (*see* D.I. 98) and applied the following legal standards in reaching its decision:

I. LEGAL STANDARDS

A. Claim Construction

"[T]he ultimate question of the proper construction of the patent [is] a question of law," although subsidiary fact-finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015). "[T]he words of a claim are generally given their ordinary and customary meaning [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (internal citations and quotation marks omitted). Although "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Id.* at 1314. "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted).

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the Court does not hold such a hearing, Defendants may raise indefiniteness again at summary judgment.

[2] D.I. cites are to docket items in C.A. No. 20-381.

[3] Defendants did not submit a tutorial.

The patent specification "is always highly relevant to the claim construction analysis . . . [as] it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. "Even when the specification describes only a single embodiment, [however,] the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence, . . . consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, courts "will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history,

including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. Expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Phillips*, 415 F.3d at 1318. Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, although extrinsic evidence "may be useful to the court," it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

B. Indefiniteness

"The primary purpose of the definiteness requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, *e.g.* competitors of the patent owner, can determine whether or not they infringe." *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002) (citing *Warner-Jenkinson Co. v. Hilton-Davis Chem. Co.*, 520 U.S. 17, 28-29 (1997)). Put another way, "[a] patent holder should know what he owns, and the public should know what he does not." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731 (2002).

A patent claim is indefinite if, "viewed in light of the specification and prosecution history, [it fails to] inform those skilled in the art about the scope of the invention with reasonable

certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). A claim may be indefinite if the patent does not convey with reasonable certainty how to measure a claimed feature. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015). But "[i]f such an understanding of how to measure the claimed [feature] was within the scope of knowledge possessed by one of ordinary skill in the art, there is no requirement for the specification to identify a particular measurement technique." *Ethicon Endo–Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312, 1319 (Fed. Cir. 2015).

Like claim construction, definiteness is a question of law, but the Court must sometimes render factual findings based on extrinsic evidence to resolve the ultimate issue of definiteness. *See, e.g.*, *Sonix Tech. Co. v. Publications Int'l, Ltd.*, 844 F.3d 1370, 1376 (Fed. Cir. 2017); *see also Teva*, 135 S. Ct. at 842-43. "Any fact critical to a holding on indefiniteness . . . must be proven by the challenger by clear and convincing evidence." *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003); *see also Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1338 (Fed. Cir. 2008).

I. THE COURT'S RULING

The Court's ruling regarding the disputed claim terms of '817, '488, '448 and '024 Patents was announced from the bench at the conclusion of the hearing as follows:

> . . . At issue in this case we have four patents and two disputed claim terms.
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> I am prepared to rule on both of the disputes. I will not be issuing a written opinion, but I will issue an order stating my rulings. I want to emphasize before I announce my decisions that although I am not issuing a written opinion, we have followed a full and thorough process before making the decisions I am about to state. I have reviewed the patents in dispute. I have also reviewed the portions of the prosecution histories, references, and the expert declarations and depositions submitted. There was full briefing on each of the disputed terms and a technology tutorial submitted by

Plaintiff. We have also had argument here today. All of that has been carefully considered.

As to my rulings, I am not going to read into the record my understanding of claim construction law and definiteness. I have a legal standard section that I have included in earlier opinions, including recently in *Roche Diabetes Care v. Insulet Corp.*, C.A. No. 20-825. I incorporate that law and adopt it into my ruling today and will also set it out in the order that I issue.

The parties have suggested different definitions of the person of ordinary skill in the art for each of the patents, but the differences have not been asserted to be relevant to the issues currently before me.[4]

Now the disputed terms.

The first term in dispute includes a dispute over what terms in claims 25 through 29 of the '488 Patent I need to construe. Plaintiff proposes the term is "analog" and argues that the proper construction is "chemical compound having structural similarity to a referenced compound." Defendants, on the other hand, argue that the terms to be construed are "naloxone analog" and "naltrexone analog" and that those terms are indefinite.

During the hearing, Plaintiff agreed that the difference between construing analog and construing naloxone or naltrexone analog is not meaningful. The real dispute is about definiteness. A finding of indefiniteness requires clear and convincing evidence, which does not exist on the present record. Although there are competing expert declarations and you all took depositions, the experts were not here today and I believe that this issue may require more fulsome discovery. So I decline to reach the merits of Defendants' indefiniteness argument at this time. Whether that means Defendants will have to raise the issue again in connection with summary judgment or that we should have a hearing at which expert testimony is presented, I have not decided. If I decide to have a hearing, I will let you know.

That being said, to the extent that Plaintiff argued today that the naltrexone and naloxone analogs claimed in claim 25 are limited to compounds that are identical to naltrexone or naloxone except for

4 For example, Defendants' expert, Dr. MacMillan, states that his opinions "would not change regardless of whichever definition of the [person of ordinary skill] used." (D.I. 89, Ex. 22 ¶ 32).

the substituents at the C6 position, that argument seems inconsistent with the other claims of the patent as we discussed today. And it appears that it is also a new argument that was not raised in the briefs, which in itself suggests that even Plaintiff is unable to figure out what the scope of the claim is. That is concerning.

For the second term, there again is a dispute over what term should be construed. Plaintiff argues that the term for construction is "unit dosage" as used in claims 1 through 7, 11, 15 through 17, 19 through 22, and 25 of the '817 Patent and in claim 1 of the '024 Patent and also claims of the '448 Patent and that the term should be construed the same across all the patents.[5] In Plaintiff's view, "unit dosage" means "co-administration, or separate but overlapping administration, of an opioid agonist in an amount sufficient to confer analgesia in a subject, and a neutral opioid antagonist in an amount sufficient to inhibit peripheral effects and insufficient to block substantial central effects of the opioid agonist in the subject." Although Defendants appear to break "unit dosage" into two terms – one from the '817 Patent and one from the '024 Patent – they seem to agree that "unit dosage" should be construed the same across the various patents.[6] And that applies to the '448 Patent as well, which is only asserted against the RedHill Defendant. Defendants propose that "unit dosage" be construed to mean "an analgesic composition in which the agonist and antagonist are co-formulated in a single dosage form, *i.e.*, in one unit" and which includes "a pharmaceutically acceptable carrier" in the same single dosage form where that is recited (*i.e.*, the '024 and '448 Patents).

The fundamental dispute is whether the "unit dosage" requires the components recited in the claim to be co-formulated into a single unit, as Defendants argue, or whether the components may be administered in separate but overlapping doses, as Plaintiff argues. Here, I agree with Defendants that "unit dosage" requires a single dosage unit that includes at least the opioid agonist and the neutral opioid antagonist together in that dosage unit, along with the pharmaceutically acceptable carrier when the claim requires it.

Starting with the term itself, the plain meaning of "unit dosage" is a dosage in the form of a unit. I think that a person of ordinary skill would understand the plain meaning of "unit dosage" to mean that the dosed components are present together in a single

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5 (D.I. 88 at 27 n.16 ("'Unit dosage' is also found in the '448 patent, claims 1, 2, 4, 5, 9, and 11. Any construction the Court determines for the '817 and '024 patents will likewise apply to the '448 patent.")).

6 (D.I. 88 at 36 n.23).

unit. Otherwise, "unit" seems to lose meaning, particularly because unit suggests similarity or togetherness.

Moving to the surrounding claim language, the context in which the term appears also supports the conclusion that the "unit dosage" requires the recited components to be present together in a single unit. For example, the asserted independent claims of the '817 Patent recite "[a] unit dosage of an analgesic composition comprising . . . an opioid agonist . . . and . . . a neutral opioid antagonist" with further requirements on the amounts. Similarly, the claims of the '024 and '448 Patents also require "[a] unit dosage of an analgesic composition" comprising an opioid agonist, neutral opioid antagonist and a pharmaceutically acceptable carrier. All claims at issue require the "unit dosage" to be an "analgesic composition," and I think that a person of ordinary skill would understand "composition" to mean a mixture of substances. Reading the term in context, a person of ordinary skill would understand that the "unit dosage" is an analgesic composition that contains a mixture of an opioid agonist and a neutral opioid antagonist together in that composition – with a pharmaceutically acceptable carrier when required. If Plaintiff were correct that "unit dosage" contemplates separate but overlapping administration of the agonist and neutral antagonist, I'm not sure that "unit dosage" or "analgesic composition" would have any meaning in the claims.

Additionally, I think that Plaintiff's argument that separate but overlapping administration is covered by "unit dosage" suffers in the context of the '024 Patent and the '448 Patent because those claims require a pharmaceutically acceptable carrier. I don't think a person of ordinary skill would understand those claims to mean a subject is to be given a pharmaceutically acceptable carrier that is separate from the pharmaceutical as long as it is given at an overlapping time. Then the carrier wouldn't really be carrying anything. Instead, a person of skill would understand "unit dosage" to mean a single dosage form that contains each of the opioid agonist, the opioid antagonist and the pharmaceutically acceptable carrier.

Plaintiff nevertheless argues that the patentees acted as their own lexicographer and specifically defined "unit dosage" to include "co-administration, or separate but overlapping administration, of an opioid agonist in an amount sufficient to confer analgesia in a subject, and a neutral opioid antagonist in an amount sufficient to inhibit peripheral effects and insufficient to block substantial central

effects of the opioid agonist in the subject."[7] I disagree. In support of that argument, Plaintiff points to two paragraphs in the beginning of the "Summary of Invention" of the three patents, but those paragraphs do not set forth a clear definition of "unit dosage." First of all, the first paragraph states that "[t]he present invention teaches the use of an opioid/opioid antagonist co-formulation, co-administration of the agonist with the antagonist, or separate but overlapping administration of the agonist with the neutral antagonist . . . ."[8] There is nothing about "unit dosage" in that sentence that makes clear to a person of ordinary skill that those three options are within the meaning of "unit dosage" as it appears in the claims. And the next paragraph, which does refer to "unit dosage," specifically refers to a "first embodiment" or "some embodiments" using a "unit dosage of an analgesic composition" that has the opioid agonist and neutral opioid antagonist.[9] Not only is this paragraph limited to embodiments, it also does not include reference to separate but overlapping administration of the agonist and the antagonist. So I don't agree with Plaintiff that these paragraphs support the conclusion that the patentees clearly defined "unit dosage" to include "separate but overlapping administration."

Moreover, I think that the specifications distinguish between instances where the agonist and antagonist are formulated together in a "unit dosage" versus administered as separate doses. As a general matter, the patents distinguish between co-formulation, co-administration and separate but overlapping administration of the agonist and neutral antagonist.[10] Although Plaintiff argues that this means all three options fall within the meaning of "unit dosage," I'm unpersuaded, particularly because there is no clear language indicating that. Moreover, the '024 and '448 Patents provide that in some embodiments, co-administration of the opioid agonist and antagonist occurs, whereas in other embodiments, "the invention includes a co-formulation product comprising an opioid agonist and a neutral antagonist (e.g., in a unit dosage)."[11] This suggests that co-administration and separate but overlapping administration is different from co-formulation in a "unit dosage." And Plaintiff also points to various places in the specifications where the "unit dosage"

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7 (D.I. 88 at 30).

8 ('817 Patent at 2:12-15; *see also* '024 Patent at 2:56-60; '448 Patent at 2:56-59).

9 ('817 Patent at 2:20-26; *see also* '024 Patent at 2:65-3:4; '448 Patent at 2:64-3:3).

10 (*See, e.g.*, '817 Patent at 2:12-15; '024 Patent at 2:57-60; '448 Patent at 2:56-59).

11 ('024 Patent at 17:24-28; '448 Patent at 17:34-8).

seems to refer to the neutral opioid antagonist alone, but this is inconsistent with the claim language "unit dosage of an analgesic composition." The antagonist alone is unable to confer analgesia. In sum, I don't think any of the portions of the specifications called out by Plaintiff are enough to change the plain meaning of "unit dosage."

Although Plaintiff relies on the examples in the '817 and '024 Patents that use co-administration of the opioid agonist and antagonist, none of those examples refer to the administration of those as a "unit dosage." Moreover, there is an example that uses co-formulation of the agonist and antagonist together in the same product.[12] Although that example does not refer to a "unit dosage," it suggests that a construction of "unit dosage" requiring co-formulation in the same product does not exclude all embodiments. Some embodiments may be excluded when there is probative evidence that "unit dosage" indicates to a person of ordinary skill that co-formulation is required and that covers at least one specific embodiment.[13]

Plaintiff also argues that claim differentiation supports its argument. In particular, Plaintiff asserts that "pharmaceutical composition," which is recited in dependent claims 9 and 18 of the '817 Patent, is narrower than "unit dosage" and requires the opioid agonist and antagonist to be present in the same single composition. The problem with Plaintiff's argument, however, is that dependent claims 9 and 18 add further limitations regarding slow-release properties. That is, it is not the case that the only thing differentiating claims 9 and 18 from their independent claims is the use of "unit dosage" vs "pharmaceutical composition." Moreover, the independent claims recite "unit dosage of an analgesic composition," and I tend to agree with Defendants that a person of ordinary skill would understand the "pharmaceutical composition" of the dependent claims is the patentees' way of referring to the "unit dosage of an analgesic composition" that is recited in the independent claims. And as for the "separately or together" language in claims 9 and 18, I think that a person of ordinary skill would understand that claim to mean either the agonist or antagonist or both may be formulated to be slow release – not that they may be administered separately.

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12 (*See* '817, '024 and '448 Patents at Example 3).

13 *See SIMO Holdings Inc. v. Hong Kong uCloudlink Network Tech. Ltd.*, 983 F.3d 1367, 1378-79 (Fed. Cir. 2021); *see also Baran v. Med. Device Technologies, Inc.*, 616 F.3d 1309, 1316 (Fed. Cir. 2010) ("It is not necessary that each claim read on every embodiment.").

> Finally, the prosecution histories. Here, several of the prosecution histories are helpful in understanding the meaning of "unit dosage." In fact, during prosecution of the '448 Patent, the patentees made clear that "unit dosage" meant a single dosage form containing the opioid agonist, antagonist and pharmaceutical carrier. In the first office action, the Examiner issued a § 112 rejection for a claim that depends from claim 1. She said, "[c]laim 1 recite[s] a unit dosage form (accordingly, it is the Examiners [sic] interpretation that the dosage form is in one unit based on previous and copending applications examined). However claim 20 recites that the unit dosage form can be either together or separate. It is not clear what applicant is claiming."[14] In response, the Applicants amended claim 20 to remove reference to "separately or together" and to simply recite that "the unit dosage is in a slow-release formulation."[15] Applicants never told the Examiner that her understanding of "unit dosage" to mean "one unit" was wrong.[16] In fact, the Applicants said that claim 20 was amended to clarify that "it is the *unit dosage* that is in a slow-release formulation."[17] The Applicants also clarified that the amended claim 1 required the amount of neutral antagonist in the unit dosage to be at least equal to the amount of opioid agonist in the unit dosage – *i.e.*, the same unit dosage.[18] I think a person of ordinary skill reading the claim amendments and the accompanying remarks would understand the Applicants used "unit dosage" to mean a single dosage form that includes all the components recited in the independent claim.
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> Continuing in the '448 Patent prosecution, after these amendments, the Examiner then rejected various claims under § 102 and 103 as anticipated or obvious over the Simon and Sadee (*i.e.*, the '488 Patent) references. The Applicants again amended their claims and said "[c]laim 1 requires a 'unit dosage of an analgesic composition' that is a combination drug, and the combination drug of claim 1 is required to include an opioid agonist" in a particular amount "as well as 'a neutral opioid antagonist'" in a particular amount.[19] This again suggests the agonist and antagonist are

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14 (D.I. 89, Ex. 14 at Appx 0394).

15 (D.I. 89, Ex. 15 at Appx 0416).

16 (*Id.* at Appx 0417).

17 (*Id.* at Appx 0419 (emphasis in original)).

18 (*Id.*; *see also id.* at Appx 0420).

19 (D.I. 89, Ex. 17 at Appx 0449; *see also* D.I. 89, Ex. 16 (Examiner's rejections)).

formulated together in that combination drug. The Applicants went further, arguing that no reference of record taught or suggested "a neutral opioid antagonist can be present in a unit dosage of a combination drug" in an amount that inhibited unwanted effects but did not prevent desired effects of the opioid.[20] And specifically attacking the Simon reference, the Applicants said that although Simon taught a combination drug with both agonist and antagonist present, it did not teach the amounts of the Applicants' invention.[21] These remarks make clear that Applicants used "unit dosage" to mean a single dosage unit where the recited agonist, antagonist and the pharmaceutically acceptable carrier were formulated together as required by the claims. And this usage is entirely consistent with the plain meaning of "unit dosage."

The '817 Patent prosecution history also includes a back-and-forth with the same Examiner that bolsters the conclusion that the claimed "unit dosage" requires a single unit. In responding to an obviousness rejection over the Sadee patent, the Applicants explained that, at the time of Sadee, it was not yet known that the opioid agonist and neutral antagonist could be formulated in a unit dosage that inhibited peripheral effects of the agonist while still allowing benefits.[22] The Applicants emphasized that "the Sadee patent teaches the separate administration of a neutral antagonist for the treatment of drug dependency in drug-dependent individuals."[23] Moreover, in the Applicants' view, the teaching of Sadee did not "translate into a combination drug with the unit dosage defined" by the Applicants' claims.[24] Indeed, the Applicants clearly stated that "[t]he subject matter defined by the pending claims is not just a matter of combining an opioid agonist with a neutral antagonist. It requires a unit dosage of both constituents, in which is included a functionally specified amount of antagonist . . . ."[25] I am not sure how a person of ordinary skill reading this could conclude anything other than the Applicants used

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20 (D.I. 89, Ex. 17 at Appx 0449).

21 (*Id.* at Appx 0449-50).

22 (D.I. 89, Ex. 12 at Appx 0364).

23 (*Id.*).

24 (*Id.*; *see also id.* at Appx 0365 ("[Sadee] utterly lacks the disclosure or suggestion that the neutral antagonist could be incorporated into a unit dosage with an opio[i]d antagonist in a specific amount . . . .")).

25 (*Id.* at Appx 0365).

"unit dosage" to mean a single unit that is formulated with both the opioid agonist and neutral antagonist.

Finally, as to the '024 Patent, the prosecution history does not contain any statements either way on this issue. But the '024 Patent is a continuation of the '448 Patent, which is a continuation-in-part of the '817 Patent. That is, the patents are all related and the parties agreed that the term "unit dosage" is to be construed the same across all three patents. And I think that the '817 Patent and especially the '448 Patent demonstrate that the Applicants used "unit dosage" to mean a single unit that contained both the recited agonist and antagonist, as well as the pharmaceutically acceptable carrier where appropriate. I want to make clear that, in using these prosecution histories, I am simply using them to gauge the Applicants' understanding of "unit dosage" as *Phillips* instructs that I may do – I am not making a finding of disclaimer.

In sum, I reject Plaintiff's attempt to include "separate but overlapping administration" in the meaning of "unit dosage." Instead, I will construe "unit dosage" to mean that the opioid agonist and neutral opioid antagonist (and pharmaceutically acceptable carrier, where appropriate) are co-formulated in a single dosage form, *i.e.*, in one unit.

Maryellen Noreika

The Honorable Maryellen Noreika
United States District Judge